

**DETAILED ACTION**

***Notice of Amendment***

In response to the arguments filed on January 26, 2010, amended claims 1, 4, 8-9, 12-13, 16 and 19 are acknowledged. The following new grounds of rejection are set forth:

***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "flange tube" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is unclear what is meant by the phrase "an endoscope control tube having a major portion of its length coaxial and coextensive with at least a portion of the endoscope control tube". How can the control tube be coaxial and coextensive with itself?

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-4, 8-10, 12 and 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "annular tube" in line 12 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "foam annular tube" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 17 recites the limitation "annular tube" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claims 3-4, 8-10, 12 and 14-18 are rejected as being necessarily dependant upon claim 1.

In claim 2, the claim limitation "coating means comprises a compressible foam member" uses the phrase "means for" or "step for", but it is modified by some structure, material, or acts recited in the claim. It is unclear whether the recited structure, material, or acts are sufficient for performing the claimed function which would preclude application of 35 U.S.C. 112, sixth paragraph.

If applicant wishes to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant is required to amend the claim so that the phrase "means for" or "step for" is clearly **not** modified by sufficient structure, material, or acts for performing the claimed function.

If applicant does **not** wish to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant is required to amend the claim so that it will clearly not be a means (or step) plus function limitation (e.g., deleting the phrase "means for" or "step for").

#### ***Claim Objections***

Claim 10 is objected to because of the following informalities: the claim should read "wherein said passage *extends radially outward* to the outer periphery of said first flange" to be grammatically correct and avoid confusion with regards to the direction of the passage. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-4, 8, 12-14, 16-17, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,569,159 to Anderson et al. in view of U.S. Patent No. 5,941,815 to Chang.

**In regard to claims 1, 13 and 17,** Anderson et al. disclose a non-invasive external control for facilitating the insertion and removal of an endoscope into a body cavity comprising: an endoscope control tube 20 having an outer and inner surface with the inner diameter 30 of the tube sized to permit sliding passage therethrough of the insertion end of an endoscope tube (see Col. 3, Lines 3-28), a first flange 22 extending outwardly from the endoscope control tube closer to the proximal end thereof, wherein the diameter of the first flange is sized to preclude insertion of the control into the body cavity of a patient, a second flange 32 extending outwardly from the endoscope control tube closer to the distal end thereof, wherein the first and second flanges act as barriers to prevent lubricant from migrating onto said control (see Figs. 1-5). Anderson et al. are silent with respect to the endoscope control tube having means for coating the endoscope tube as it passes through the annular tube with a lubricant. Chang discloses a sigmoid splint 10 that includes an elongated tubular member 12 with an outer surface 14 and an inner surface 16. Tubular member 12 has a distal end 18 which enters the

human body and a proximal end 20 which has a mechanism for preventing complete entry into the human body during the procedures described herein, such as an outside diameter at the proximal end 20 being larger than the outside diameter of distal end 18. The inside diameter of tubular member 12 must be greater than the outside diameter of the endoscope to be used with splint 10. Located at or near the distal end 18 of tubular member 12 is distal seal 22 having an opening 23, an external surface 24 and an internal surface 26. The external surface 24 of distal seal 22 attaches to inner surface 16 of tubular member 12 (see Fig. 1 and Col. 7, Lines 30-67). The diameter of opening 23 should be substantially equal to or slightly less than the outer diameter of the endoscope, such that distal seal 22 closes on the endoscope to prevent entrapment of colonic wall material between the endoscope and splint 10. The tightness of distal seal 22 should be such that the interface of the seal and the endoscope will not entrap mucosa and/or will not allow the free flow of fluid from inside the splint. For lubrication purposes, it may be beneficial if the interface of the seal and the endoscope will allow some fluid to trickle out onto the portion of the endoscope beyond the splint (see Col.8, Lines 28-50). **In regard to claims 3-4, 12, 14 and 21**, Chang discloses the lubrication means as a foam rubber positioned at one end within the control tube (see Figs. 2-3). It would have been obvious to one skilled in the art at the time the invention was made to provide lubrications means in the apparatus of Anderson et al. to ease insertion of the scope therethrough and avoid problems with excessive friction as taught by Chang.

**In regard to claim 8**, Anderson et al. disclose a non-invasive external control for facilitating the insertion and removal of an endoscope into a body cavity, wherein the

distance between the first and second flanges provide a sufficient length along the endoscope control tube for hand-gripping (see Fig. 2).

**In regard to claims 16 and 19,** Anderson et al. disclose a non-invasive external control for facilitating the insertion and removal of an endoscope into a body cavity wherein said second flange is shaped for gripping as end finger rest to assist in controlling the insertion and removal of the endoscope tube (see Fig. 2).

Claims 1, 3-4, 8-10, 12-15, 17-18 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,941,815 to Chang in view of U.S. Patent No. 6,503,192 to Ouchi.

**In regard to claims 1, 8, 13 and 16,** Chang discloses a non-invasive external control for facilitating the insertion and removal of an endoscope into a body cavity comprising: an endoscope control tube 14 having an outer and inner surface with the inner diameter of the tube sized to permit sliding passage therethrough of the insertion end of an endoscope tube (see Figs. 5a-d), a first flange 20 extending outwardly from the endoscope control tube closer to the proximal end thereof, wherein the diameter of the first flange is sized to preclude insertion of the control into the body cavity of a patient (see Figs. 1-3), the endoscope control tube having means 22/32 and/or 60 for coating the endoscope tube as it passes through the annular tube with a lubricant. Anderson et al. are silent with respect to the endoscope control tube having, a second flange extending outwardly from the endoscope control tube closer to the distal end thereof. Ouchi teaches of an analogous endoscopic guide wherein a cylindrical body 10a is provided with a small outer diameter portion 10c in the vicinity of the end opening

10b, so that the insertion facilitating device 10 can be prevented from slipping out of the anus. Since the outer small diameter portion 10c is pressed and firmly held by the anal sphincter, the insertion facilitating device 10 can be stably held in the anus during the insertion or removal of the flexible tube 11 in or from the insertion facilitating device. Moreover, as shown in FIG. 5, it is possible to provide a tapered portion 10d whose diameter is gradually reduced toward the distal end 10g of the cylindrical body 10a that is to be inserted in the patient's body, so that the insertion of the insertion facilitating device 10 into the patient's anus can be facilitated due to the tapered end (conical end) 10d (see Figs. 3-7 and Col. 3, Line 55 – Col. 4, Line 22). It would have been obvious to one skilled in the art at the time the invention was made to provide a second flange at the distal end of the control tube of Chang to ensure stability of the insertion guide during a surgical procedure and passage of an endoscope therethrough as taught by Ouchi.

**In regard to claim 3,** Chang discloses a non-invasive external control for facilitating the insertion and removal of an endoscope into a body cavity, wherein said coating means comprises a compressible foam member 22, 32 impregnated with a lubricant positioned to engage an endoscope tube as it moves through the control (see Col. 6, Lines 1-16).

**In regard to claim 4,** Chang discloses a non-invasive external control for facilitating the insertion and removal of an endoscope into a body cavity, wherein the foam member comprises a radially extending flange tube at least partially positioned at one end within the endoscope control tube and having an inner uncompressed diameter

substantially equal to the outer diameter of an endoscope tube intended to be controlled (see Figs. 2-3).

**In regard to claim 9,** Chang discloses a non-invasive external control for facilitating the insertion and removal of an endoscope into a body cavity, wherein said first flange has a passage extending radially from the inner surface of said endoscope control tube outwardly through the flange, wherein said passage feeds a lubricant into the interior of the endoscope control tube (see Figs. 1-3 and Col. 5, Lines 34-62 and Co. 9, Lines 13-36).

**In regard to claim 10,** Chang discloses a non-invasive external control for facilitating the insertion and removal of an endoscope into a body cavity, wherein said passage extending radially to the outer periphery of said first flange (see Figs. 1-3 and Col. 5, Lines 34-62 and Co. 9, Lines 13-36).

**In regard to claim 12,** Chang discloses a non-invasive external control for facilitating the insertion and removal of an endoscope into a body cavity, wherein the compressible foam member comprises an endoscope control tube having a major portion of its length coaxial and coextensive with at least a portion of said endoscope control tube (see Figs. 2-3).

**In regard to claim 14,** Chang discloses a non-invasive external control for facilitating the insertion and removal of an endoscope into a body cavity, wherein the foam annular tube is positioned interior the annular tube (see Fig. 2-3).

**In regard to claim 15,** Chang discloses a non-invasive external control for facilitating the insertion and removal of an endoscope into a body cavity, wherein the control has means for opening the control along its length (see Fig. 6).

**In regard to claims 17 and 21,** Chang discloses a non-invasive external control for facilitating the insertion and removal of an endoscope into a body cavity, wherein said annular tube is compressible to control said means for coating the endoscope tube with a lubricant (see Col. 6, Lines 1-16).

**In regard to claims 18 and 20,** Chang discloses a non-invasive external control for facilitating the insertion and removal of an endoscope into a body cavity, further comprising a reservoir for holding the lubricant, wherein said reservoir is located within said first flange (see Figs. 1-3 and Col. 5, Lines 34-62 and Col. 9, Lines 13-36).

***Response to Arguments***

Applicant's arguments with respect to claims 1, 3-4, 8-10 and 12-21 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Matthew J Kasztejna/  
Primary Examiner, Art Unit 3739

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